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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,819	05/23/2002	Maria Salome Soares Pais	08685.0001	1528
22852	7590	10/04/2004	EXAMINER	
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER LLP 1300 I STREET, NW WASHINGTON, DC 20005			PAK, YONG D	
			ART UNIT	PAPER NUMBER
			1652	

DATE MAILED: 10/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,819

Applicant(s)

SOARES PAIS ET AL.

Examiner

Yong D Pak

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 18 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 9-11 and 14-16 is/are rejected.
- 7) ☒ Claim(s) 4-8, 12, 13, 17, 20 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12/7/2001.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 of PCT/PT00/00007. The preliminary amendment filed on December 7, 2001, amending claims 1, 11, and 19, has been entered.

Claims 1-21 are pending.

Election/Restrictions

Applicant's election of Group I in the reply filed on July 19, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 18-19 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on July 19, 2004.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on December 7, 2001 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

Claims 4-5, 12-13 and 20-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). Accordingly, the claims 4-5, 12-13 and 20-21 have not been further treated on the merits.

Claims 5-8, 13, 17 and 20-21 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims 5-8, 13, 17 and 20-21 have not been further treated on the merits.

Claims 2-10, 12-17 and 20-21 lack periods at the end of the claim.

In claim 4, the word "claim" is missing in front of "1".

Specification

The amendment filed on December 7, 2001 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: a DNA molecule encoding cardosin A derived from *Cynara cardunculus* as incorporated by reference on

Art Unit: 1652

pages 1-6 (Faro et al. Journal of Biological Chemistry, Vol. 274, No. 40, pp. 28274-28729, 1999 – form PTO-892).

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 9-11 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are drawn to a DNA encoding a plant aspartic proteinase derived from any plant source and methods of producing plant aspartic proteinase derived from any plant source. Therefore, these claims are drawn to a method of using a genus of aspartic proteinases having any structure. The specification only teaches one representative species of plant aspartic proteinase, a cyprosin derived from *Cynara cardunculus*. One species is not enough to describe the whole genus and there is no evidence on the record of the relationship between the structure of cyprosin from *C. cardunculus* and an aspartic proteinase derived from any plant source or a cyprosin from another plant source.

Although the originally foreign filed application PT 102318 B mentions a method of producing cardosin, the disclosure does not teach any DNA molecules encoding a cardosin. A preliminary amendment filed with the instant application (December 7, 2001) incorporates by reference a DNA molecule encoding a cardosin. Nevertheless, the instant specification only describes a DNA molecule encoding one cardosin, cardosin A derived from *C. cardunculus*. Therefore, the specification fails to describe a representative species of the genus of plant aspartic proteinases or plant cardosins or plant cyprosin. There is no evidence on the record of the relationship between the structure of cardosin A from *C. cardunculus* and an aspartic proteinase derived from any plant source or a cardosin A or B from another plant source.

Claim 11 is also drawn to a DNA molecule encoding a plant aspartic proteinase or a part thereof. The genus of DNA that comprise these above parts/fragments/portions of DNA encoding a plant aspartic proteinase is a large variable genus with the potentiality of encoding many different proteins. Therefore, many structurally and functionally unrelated DNA are encompassed within the scope of these claims, including partial DNA sequences. The specification fails to describe any other representative species by any identifying characteristics or properties and fails to provide any structure: function correlation present in all members of the claimed genus.

Given this lack of description of the representative species encompassed by the genus of the claims, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the inventions of claims 1-3, 9-11 and 14-16.

Claims 1-3, 9-11 and 14-16 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA molecule encoding a cyprosin derived from *C. cardunculus* and methods of producing said enzyme, does not reasonably provide enablement for a DNA encoding a plant aspartic proteinase or other cyprosin having any structure. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

To practice the invention, the structure of an aspartic proteinase must be known. However, the specification only teaches a DNA molecule encoding cyprosin and cardosin A derived from *C. cardunculus*. Despite knowledge in the art for the isolation of amino acids/nucleic acids, the specification fails to provide guidance regarding how to isolate other DNA molecules whose sequence is different to the DNA molecules encoding cyprosin and cardosin A derived from *C. cardunculus*. Therefore, the breadth of these claims is much larger than the scope enable by the specification.

Art Unit: 1652

The predictability as to the level of conservation between the disclosed sequences and those of other plant aspartic proteinase is extremely complex. While recombinant techniques are available, it is not routine in the art to screen large numbers of amino acids where the expectation of obtaining similar sequences is unpredictable. The amino acid sequence determines the structural and functional properties of an enzyme. Knowledge of which sequences can be altered or removed and still result in similar protein activity is well outside the realm of routine experimentation.

The quantity of experimentation in this area is extremely large since there is significant variability in the structure of all plant aspartic proteinase. It would require significant study to identify any aspartic proteinase and would be an inventive, unpredictable and difficult undertaking. This would require years of inventive effort, with each of the many intervening steps, upon effective reduction to practice, not providing any guarantee of success in the succeeding steps.

Therefore, one of ordinary skill would require guidance in order to use any plant aspartic proteinase having unknown structure in a manner reasonable correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1652

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 9-11 and 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by White et al.

White et al. (form PTO-1449 – see attached for first date available to public) teaches a vector and host cell comprising DNA encoding a plant aspartic proteinase, a cyprosin derived from *C. cardunculus* and a method producing said enzyme (abstract and pages 16685-16686). White et al. teaches a DNA construct comprising pro-sequences joined to the reading frame of the DNA encoding a plant aspartic proteinase (pages 16685-16686). Therefore, the teachings of White et al. anticipate claims 1-3, 9-11 and 14-16.

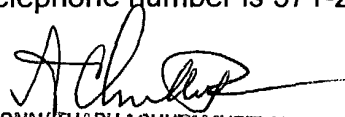
No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 571-272-0928. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Yong D. Pak
Patent Examiner


PONNATHAPU ACHUTAMURTHY
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1300